

## REMARKS

The Official Action of 28 August 2007 has been carefully considered and reconsideration of the application as amended is respectfully requested.

The courtesy of Examiners Alicia Hughes, Esq. and Dr. Ardin Marschel in conducting an interview with Dr. C.G. Wang, Dr. Tom Vullo and Applicant's undersigned representative on 20 February 2008 is gratefully acknowledged. The Interview Summary which issued at the interview accurately reflects what transpired as discussed below.

The specification has been amended to correspond with the disclosure in original claims 115-117, the embodiment of the invention which the Applicant elected in response to the restriction action of 16 December 2005. See MPEP 608.01(o). In this embodiment, rose bengal is used as a compound comprising pre-selected elements (iodine) for administration to a subject without the compound being complexed with a carrier compound (see original claims 115-117 and paragraph [0064] of the specification as filed).

Moreover, as discussed in paragraph [0060] of the specification as filed, rose bengal is a food dye and thus its characterization as a "chemotherapeutic agent" in the specification as filed at paragraph [0059] is not in accordance with the standard dictionary meaning of the term "chemotherapeutic agent". The latter paragraph has now been amended to eliminate this erroneous use of the

term “chemotherapeutic agent” to describe rose bengal. Both the error and the correction would have been clear to one of skill in the art from the application as filed (including paragraph [0060] and original claims 115-117, which describe the embodiment of the invention now being claimed without using the term) whereby the amendment does not introduce new matter. See MPEP 2163.07(II) (“An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction.”).

Claim 115 has been amended as courteously suggested by the Examiners to clarify that the claimed method is directed to the preferential destruction of tumor cells, as opposed to normal cells, in a subject. Support for the recitations in claim 115 appears in the specification as filed at, e.g., paragraphs [0065] and [0038], which describe that the irradiating is confined to a specific tumor location so as to localize damage caused by the irradiating and to minimize damage to normal cells of the subject. Claim 115 has also been amended to incorporate the subject matter formerly in claim 123, now canceled.

Claims 136-147 have been added more completely to define the subject matter which Applicant regards as his invention. Claim 136 has been drafted in Jepson format in accordance with the preference expressed in 37 CFR 1.75(e), and recites in the preamble the steps known in the prior art from Cash, Jr. et al, US Patent 6,366,801 (referenced in paragraph [0004] of the specification). As described in Cash et al, and as discussed in the interview and further below,

radiosurgery with the use of a contrast agent to enhance the effectiveness of x-rays was known in the prior art as **a tool** in treating tumors. What was not known was the improved use of this tool with the combined administration of rose bengal and the use of monochromatic line emission x-rays having an energy above and near the K-absorption edge or the L-absorption edge of iodine present in the rose bengal so as to cause emission of Auger electrons from the rose bengal so as preferentially to destroy tumor cells, as opposed to normal or healthy cells, in a specific location where a tumor is present (see specification at paragraph [0065]).

Support for the recitations in claims 136 and 142 appears in the specification as filed at, for example, paragraph [0038]. Support for the recitations in claims 137 and 144 appears in the specification as filed at, for example, paragraph [0034]. Support for the recitations in claim 143 appears in the specification as filed at, for example, paragraph [0028]. Support for the recitations in claims 138-140 and claims 145-147 appears in the specification as filed at, for example, paragraph [0065]. See, also, paragraph [0052] (describing the "leaky" vascularity of tumors compared to normal tissue, which results in a contrast agent pooling in the extracellular spaces of cancerous tissue).

Claims 115, 122 and 130 were rejected under 35 USC 103(a) as allegedly being unpatentable over Cash et al in view of Wang and Ariel et al. This recitation was not applied against the subject matter formerly in claim 123, which subject matter has now been incorporated into the independent claims, whereby

the amendment to the claims respectfully removes the basis for the rejection.

Claims 115 and 122-135 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

As discussed at the interview, the claimed invention provides a tool for the **preferential or selective** removal of tumor cells (as opposed to normal or healthy cells) by radiosurgery that is similar, by way of example, to a surgical method for the removal of tumor cells with use of an improved scalpel. Just as claims to a method for selective removal of tumor cells with an improved scalpel would not be considered to be non-enabling simply because it may not be possible to remove all tumor cells in a tumor using the scalpel without also removing healthy cells, a method for preferential destruction of tumor cells by radiosurgery cannot be considered to be non-enabling simply because it may not be possible to destroy all tumor cells in a tumor using the radiosurgery method without also destroying some healthy cells. In each case, those of skill in the art would be able to determine without undue experimentation those tumors, if any, which may not be operable with the selected method (tool). See, also, MPEP 2164.08(b) ("The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled.").

This is especially true in a case where, as here, the state of the art provides a tremendous amount of guidance in the use of radiosurgery as a tool

for treating tumors. As discussed in the interview, this is shown by the Cash et al reference that has been cited of record. It is also shown by the Cecil Textbook of Medicine, also cited of record, at pages 1061-1062 ("Compared with surgery, radiation therapy has distinct advantages in the locoregional treatment of cancer. Radiation causes less acute morbidity and can be curative for some specific sites while preserving organ or tissue structure and function."). Thus, Applicant respectfully submits that the state of the art establishes that the application is enabling for the invention as claimed. See MPEP 2164.05(a) ("The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification.").

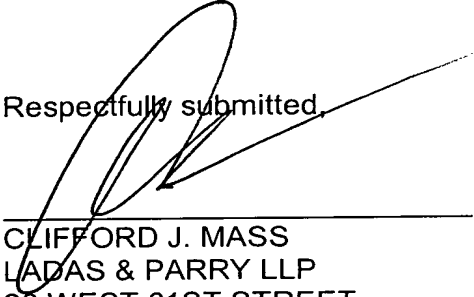
In any event, as also discussed at the interview, the USPTO has respectfully not met its initial burden to establish a reasonable basis to question the enablement provided for the claimed invention in the specification as filed. As stated in MPEP 2164.04, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure."

In the present case, the only reason provided by the Examiner for the

rejection is an alleged teaching in Goldman et al that there is no one specific chemotherapeutic agent that is effective to treat all types of cancers. However, as discussed in the interview, the claimed invention is **not** directed to a chemotherapeutic agent but to an improved method for radiosurgery. Accordingly, and as discussed above, the provided reason is respectfully not applicable to the invention as claimed and the USPTO has respectfully not met its initial burden of establishing even a *prima facie* case of lack of enablement for the claimed invention.

In view of the above, Applicant respectfully submits that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted. Nevertheless, if the Examiner believes that any further amendment to the claims is needed to place the application into allowable form she is respectfully invited to telephone the undersigned to discuss.

Respectfully submitted,



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CLIFFORD J. MASS  
LADAS & PARRY LLP  
26 WEST 61ST STREET  
NEW YORK, NEW YORK 10023  
REG. NO.30,086(212)708-1890